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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/540,086 | 12/28/2005 | Krishna Prasad Hanumanthappa | 4544-051936 | 6434 |

28289 7590 02/17/2010

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| EXAMINER | |
|---|---|
| BAUSCH, SARAE L | |
| ART UNIT | PAPER NUMBER |
| 1634 | |
| MAIL DATE | DELIVERY MODE |
| 02/17/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/540,086 | HANUMANTHAPPA ET AL. | |
| | Examiner | Art Unit | |
| | SARAE BAUSCH | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *25-46* is/are pending in the application.

4a) Of the above claim(s) *25, 29-30, 45-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-28 and 31-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Status*

1. Currently, claims 25-46 are pending in the instant application. Claims 25, 29, 30, 45, and 46 have been withdrawn from consideration as being drawn to a nonelected invention. Claims 26-28 and 31-44 are under examination. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are reiterated from the previous office action. Response to arguments follow. This action is FINAL.

### *Election/Restrictions*

2. Applicant's election with traverse of group II, SEQ ID NO 1, 2, and 7 in the reply filed on 12/07/07 and 05/05/08 is acknowledged. The traversal is on the ground(s) that Cohey et al. does not teach or suggest the claimed invention the differentiation of mycobacteria species, M. tuberculosis/M.bovis based on target gene encoding for histone like proteins such as hupB. This is not found persuasive because the claims do not require the differentiation of M. tuberculosis and M. bovis the claims are drawn to a hupB gene comprise of SEQ ID NO 8 or 7 as claimed in claim 25 (claim 45-46) and thus the sequence of SEQ ID NO 8 or 7 will inherently have the property of differentiation of M. tuberculosis and M. bovis. SEQ ID NO 7 and SEQ ID NO 8 are disclosed in Cohavey. Furthermore, the special technical feature of group I and II was considered to be the hupB gene of a mycobacterium species not differentiation of mycobacteria species as asserted by applicant, the hupB gene is disclosed in Cohavey thus, the technical feature linking the groups does not constitute a special technical feature and thus is not a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 24, 29-30, and 45-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/07/2007.

4. Claims 26-28, 31-44 are under examination with regard to SEQ ID NO 1-2.

***Drawings***

5. The drawings are acceptable.

***Maintained Rejections***

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 26-28, 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamerbeek et al. (J Clin Microbiol, 1997, vol 35, pp. 907-914) in view of Furugen (Microbial Pathogenesis 2001, vol. 30, pp 129-138), Hogan et al. (US Pat. 5,541,308, July 30, 1996) and Buck et al (Biotechniques (1999) 27(3):528-536).

Kamerbeek et al. teach simultaneous detection and differentiation of M. tuberculosis by amplification of a DR region with known interspersed spaces repeats by PCR. Kamerbeek teach amplified DNA was used directly for hybridization to differentiation different hybridization patterns to differentiate mycobacterial strains and species (see pg. 910, 1st column). Kamerbeek teaches that the DR region had five absent spaces and distinguished M. bovis from M. tuberculosis (see pg. 910, 2nd column), thus teaches differentiation consists in determining smaller size of amplified fragments. Kamerbeek teach obtaining DNA from bacterial cultures, sputum, and other clinical specimens of patients, followed by amplification of DNA and hybridization of DNA probe and detection of hybridization(see pg. 909). Kamerbeek does not teach amplification of hupB, primers SEQ ID NO 1, 2, probe SEQ ID NO 7, or amplified fragments of 618, 645, 291, 318, 89, 116, or 27bp.

However, Furugen et al. teach the sequence of hupB, MDP1, for M. bovis and M. tuberculosis. Furugen et al. teaches that there is a 9 amino acid insertion region in M. tuberculosis, which is not found in M. bovis, M. leprae or other unrelated microorganisms (see figure 6). Thus, Furugen teaches the hupB differentiations between M. bovis and M. tuberculosis.

Hogan et al. (herein referred to as Hogan) teaches the use of specific primers col. 6-7, lines 50-67, lines 1-12, and furthermore provides specific guidance for the selection of primers,

> "Once the variable regions are identified, the sequences are aligned to reveal areas of maximum homology or 'match'. At this point, the sequences are examined to identify potential probe regions. Two important objectives in designing a probe are to maximize homology to the target sequence(s) (greater than 90% homology is recommended) and to minimize homology to non-target sequence(s) (less than 90% homology to non-targets is recommended). We have identified the following useful guidelines for designing probes with the desired characteristics.
> First, probes should be positioned so as to minimize the stability of the probe:nontarget nucleic acid hybrid. This may be accomplished by minimizing the length of perfect complementarity to non-target organisms, avoiding G and C rich regions of homology to non-target sequences, and by positioning the probe to span as many destabilizing mismatches as possible (for example, dG:rU base pairs are less destabilizing than some others). Second, the stability of the probe:target nucleic acid hybrid should be maximized. This may be accomplished by avoiding long A and T rich sequences, by terminating the hybrids with G:C base pairs and by designing the probe with an appropriate Tm. The beginning and end points of the probe should be chosen so that the length and %G and %C result in a Tm about 2-10$^{o}$C higher than the temperature at which the final assay will be performed. The importance and effect of various assay conditions will be explained further herein. Third, regions of the rRNA which are known to form strong structures inhibitory to hybridization are less preferred. Finally, probes with extensive self complementarity should be avoided."

Hogan teaches that "while oligonucleotide probes of different lengths and base composition may be used, oligonucleotide probes preferred in this invention are between about 15 and about 50 bases in length" (col. 10, lines l3-15). Oligonucleotides complementary to sequences adjacent to the probe regions were synthesized and used in the hybridization mix according to Hogan et al.,U.S. Pat. No. 5,030,557., filed Nov. 24, 1987, entitled "Means and Method for Enhancing Nucleic Acid Hybridization (the "helper " patent application). Hogan teaches that oligonucleotide probes may be labeled by any of several well known methods such as radioisotopes, non-radioactive reporting groups, non-isotopic materials such as fluorescent

molecules (col. 10, lines 45-60). Hogan teaches that probes may be labeled using a variety of labels, as described within, and may be incorporated into diagnostic kits.

Buck expressly provides evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable expectation of success.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention was made to perform the method of amplification of a region that differs in size between mycobacterial species using clinical samples and cultures of DNA as taught by Kamerbeek and further modify the method to include amplification of the HupB gene as Furugen teaches that hupB gene has a 9 amino acid sequence variation in mycobacterial species. Due to

the teaches of Furugen that the hupB gene has a 9 amino acid sequence variation in M. tuberculosis and M. bovis, the ordinary artisan would have been motivated to substitute amplification and hybridization of the DR region as taught by Kamerbeck and amplify the hupB gene specifically to include the 9 amino acid variation region to distinguish M. tuberculosis and M. bovis, as taught by Kamerbeck. From the teachings of the prior art, the ordinary artisan would have been taught that M. tuberculosis and M. bovis could be differentiated by amplification of DNA that varies in length between the two species and detection could be performed by hybridization of a probe to detect the amplicons. Therefore the ordinary artisan would have been motivated to use additional regions of DNA that vary between M. tuberculosis and M. bovis, including hupB, as taught by Furugen and it would have been prima facie obvious to the ordinary artisan at the time the invention was made to improve the method of Kamerbeck to include amplification of the hupB, specifically the region that comprises the 9 amino acid insertion as taught by Furugen, thus the generating multiple different size amplicons including a minimal length of 27 nucleotides. Furthermore, to practice the method, the ordinary artisan would have been motivated to generate a number of different primers and probes for use in the method including SEQ ID NO. 1 and 2 and hybridization probe SEQ ID NO. 7.

Designing primers and probes which are equivalents to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes and primers, see Hogan et al. Moreover there are many internet web sites that provide free downloadable software to aid in the selection of primers drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to

design primers and probes. As discussed above, the ordinary artisan would be motivated to have designed and tested new primers or probes to obtain additional oligonucleotides that function to differentiation M. bovis and M. tuberculosis by amplification of the hupB gene and identify oligonucleotides with improved properties. The ordinary artisan would have a reasonable expectation of success of obtaining additional probes from for the region of the hupB gene to include the 9 amino acid insertion in M. tuberculosis provided by Furugen. Thus, for the reasons provided above, the ordinary artisan would have designed additional probes, including labeled probes and varying sized amplicons using the teachings in the art at the time the invention was made.

***Response to Arguments***

9. The response traverses the rejection on pages 4-6 of the remarks mailed 10/22/2009. The response asserts that Kamberbeek teach simultaneous detection and differentiation of M tuberculosis amplification of a DR region by PCR and assert the method is focused on analysis of a direct repeat region in the DNA which is not located near the hupB gene. The response asserts that the hupB gene is located more than 22,000 bp downstream from the DR region and it would have not been obvious to one of ordinary skill in the art to assume that similar conclusions and differentiations could be made about the DR region and hupB gene. This response has been thoroughly reviewed but not found persuasive. Kamberbeek was not cited to teach detection of the hupB gene, nor provide motivation to detect the hupB gene thus the argument with respect to the hupB gene located 22,000 bp downstream of the DR region is moot. Kamberbeek was cited because Kamberbeek teaches simultaneous detection and differentiation of M. tuberculosis by PCR thus demonstrating that it was well known in the art to detect and differentiate

mycobacterium strains and species by amplification and specifically by amplification of a known diverse region of the genome. Thus based on the teachings of Kamberbeek coupled with the teaching of Furugon that the hupB gene is known to have diverse sequence between mycobacterial strains, the ordinary artisan would have been motivated to detect the hupB gene to differentiate mycobacterial strains, specifically M. bovis and M. tuberculosis.

` The response asserts that the ordinary artisan would not have known to utilize different sizes of the hupB gene and its homologues M. bovis by examining the DR region. The response asserts that the specific design of primers SEQ ID NO 1 and 2 are used for differentiation of mycobacterium species arose through the analysis of the hupB gene of M. tuberculosis and M. bovis and not through the analysis of the upstream genome related to the DR region. The response asserts that because the hupB gene is not located near DR region, the teaching of Kamberbeek would not provide the methods including the primers of the claimed invention used for differentiation based on the hupB gene. This response has been thoroughly reviewed but not found persuasive. The rejection is not based on analysis of the DR region of Kamberbeek. The rejection is based on the teaching that Kamberbeek teaches analysis of differentiating mycobacterium by amplifying a known diverse region of the genomic sequence. Furugen was cited to teach that the hupB gene was known to have differences in the genomic sequence between M. bovis and M. tuberculosis thus the ordinary artisan would have been motivated to substitute the amplification of the DR region for amplification of the hupB gene to differentiate M. bovis from M. tuberculosis. The rejection is not based on analysis of the DR region but that it would have been obvious to detect the hupB gene using the general methodology taught by

Kamerbeek, the teaching of amplifying a known diverse region of genomic DNA to differentiate two species.

The response asserts that Furugen relates to function of the DNA binding protein derived from M. bovis and one reading Furugen would focus on the protein not the exploitation of the differences between the closely related mycobacterial species. This response has been thoroughly reviewed but not found persuasive. Furugen teaches the differences between the MDP1 gene, which is the hupB gene and therefore Furugen teaches differences in the gene between closely related mycobacterial species. It is noted that determination of obviousness is on what a person of ordinary skill in the pertinent art would have known at the time of the invention and on what a person would have reasonably expected to have been able to do in view of that knowledge. Thus, a person of ordinary skill in the art based on the teaching of Kamberbeek and Furugen would have expected to be able to adapt the differentiation of mycobacterial strains using PCR of diverse genomic sequences using the DR region of Kamberbeek with the teaching of Furugen that the MDP1 (hupB) gene is diverse among mycobacterial species and thus because Furugen teach and provides suggestion to analyze another diverse region of genomic DNA, specifically the hupB gene, the ordinary artisan would have modified the teaching of Kamberbeek to include amplification of the hupB gene, based on the teaching of Furugen. The ordinary artisan based on the teaching in the art of hupB variation of sequences, by Furugen along with the ability to differentiate mycobacterium by PCR amplification of a diverse region of genomic DNA, taught by Kamberbeek, the ordinary artisan would have differentiated mycobacterium, specifically M. bovis and M. tuberculosis using PCR amplification of the hupB gene.

The response asserts that none of Furugen, Hogan, or Buck provides any reason to believe that the method of differentiation based on the DR region would teach or suggest the claimed primers and probes. This response has been thoroughly reviewed but not found persuasive. The rejection is not based on the teaching that Furugen, Hogan, or Buck would provide primers or probes to differentiation the DR region, the rejection is based on the teaching of Kamberbeek that differentiation of mycobacterium by PCR amplification is performed on a diverse region of genomic DNA, Furugen teaches that the hupB gene is diverse among mycobacterium, and thus the ordinary artisan would have had a reasonable expectation of success and obtain predictable results that amplification of the hupB gene including using primers and probes of SEQ ID NO 1-2 and 7 specific for the hupB gene would differentiation M. tuberculosis and M. bovis.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

10. Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamerbeek et al. in view of Furugen, Hogan et al. and Buck et al as applied to claims 26-28, 31-41 above, and further in view of Taylor (J. Clin. Microbiol. 1997, vol. 35, pp. 79-.85) and Cuende et al. (Med Clin (Barc) 1995, vol. 104, pp. 207-10 (article in spanish), abstract only).

The method of Kamerbeek in view of Furugen, Hogan, and Buck is set forth in section 10 above. Kamerbeek in view of Furugen, Hogan, and Buck does not teach restricting the amplified fragment with HpaII, separating the restricted fragments by electrophoreses, and detecting the restricted fragments, nor teach lengths of 280 and 150bp or 253 and 150bp.

Taylor teaches PCR-restriction fragment length polymorphism to identify 28 species of clinically encountered mycobacteria for identification. Taylor teaches digestion of amplified products using Bst EII and HaeII followed by separation by gel electrophoresis and identified by staining with ethidium bromide (see pg. 80, 2nd column and figure 2).

Cuende et al. teaches amplification followed by RFLP analysis using HpaII and analysis on gel electrophoresis to generate 13 different patters to type clinical isolated of mycobacteria (see abstract).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of Kamerbeek in view of Furugen, Hogan, and Buck to include a step of RFLP analysis including digestion with HpaII followed by analysis by electrophoresis and ethidium bromide staining as Taylor teaches that PCR-RFLP is a rapid identification procedure of mycobacteria species. The ordinary artisan would have been motivated to improve the method of Kamerbeek in view of Furugen, Hogan, and Buck to include HpaII analysis and visualization by gel electrophoresis because Taylor teaches the PCR-RFLP method is a reliable technique that has the ability to identify rapidly mycobacteria and is easy to incorporate into the routine work flow of a microbiology laboratory (see pg. 84, last para) additionally, the ordinary artisan would have been motivated to include additional routine restriction enzyme, including HpaII and routine electrophoresis of nucleic acids, including 12% polyacrylamide gel, to thereby optimize experimental conditions and maximize experimental results. In performing the method of Kamerbeek in view of Furuguen, Hogan, and Buck and further in view of Taylor and Cuende the ordinary artisan would have generate additional fragment lengths, including 280 bp, 150bp, 253 bp, and 150bp for analysis. It is noted that *In re*

*Aller*, 220 F. 2d 454, 456, I05 USQ 233,235 states where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

***Response to Arguments***

11. The response traverses the rejection on pages 6-7 of the remarks mailed 10/22/2009. The response asserts that neither Taylor nor Cuende account for the deficiencies of the teaching of Kamberbeek, Furugen, Hogan and Buck. The response asserts that neither Taylor nor Cuende provide any reason to believe that the method of differentiation of the DR region would teach or suggest the primers SEQ ID NO 1 and 2 or probe SEQ ID NO 7. This response has been thoroughly reviewed but not found persuasive. Taylor nor Cuende were cited to teach amplification of the DR region using SEQ ID NO 1, 2, or probe SEQ ID NO 7. Kamberbeek in view of Furugen, Hogan and Buck teach differentiation of M. Bovis and M. tuberculosis by amplification the hupB gene by amplification using SEQ ID NO 1, 2 and probe SEQ ID NO 7, as address above.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

***Conclusion***

12. No claims are allowable.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner, Art Unit 1634